

Baxter

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March 30, 2000

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Citizen Petition 00P-0498/CP 1

Request for Exemption for the Swan-Ganz Pacing Catheters and Probes

Amendment

Baxter is submitting the following additional information in support of the Citizen Petition for the Swan-Ganz Pacing Catheters and Probes. In discussions with Kent Berthold of the Office of Compliance, he indicated that FDA was unclear regarding the amount of time required to purchase and implement a protected lead and adaptor. To clarify this issue, Baxter is providing a summary of the steps that are required to implement a change such as this, thus justifying Baxter's previous request for a 180-day variance:

- A compatible protected lead/shroud would be identified from the list of suppliers identified by the FDA.
- Samples of the protected lead/shroud would be shipped to Baxter.
- A method of attachment of the protected lead/shroud to the catheter would be identified and feasibility evaluation of the lead/shroud completed.

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- Documentation for the protected lead/shroud would be generated to allow components to be purchased. In addition, documentation for the modified catheters/probes would be generated to allow building of units for design verification (note: documentation for each model would be generated, thus resulting in a large number of documents that would be created/modified)..
- A supplier audit would be conducted to meet the supplier quality requirements.
- An order for components would be placed and shipped to Baxter (lead time for component shipment depends on the supplier).
- A design verification protocol would be written and approved. Catheters would be assembled per the protocol. Testing of the devices would be conducted and a report would be generated and approved.
- Labeling would be created/modified for the modified product, including changes to the illustrations and instructions as needed. The English text would be approved and the modified text sent out to be translated into seven languages (the labeling is multilingual for these products). Artwork for the final labeling would be created, approved and implemented on the documentation system.
- The documentation for the components and modified devices would be finalized and released to allow product to be built for market release.
- Product would be built, sterilized and degassed (aerated) prior to shipment.
- Customers would be notified of new model numbers and the need to purchase adaptors. Due to the number of personnel at medical institutions involved in ordering and using the products, notification of the customers would include not only the device users (to ensure that they understand the changes being implemented and how it will affect their use of the devices) but also the purchasing department (to make sure that the correct products were ordered such that all components of the system are available at the same time).

- For international customers, requirements for re-registration of the modified devices would be evaluated and pursued. This may require obtaining an updated Certificate for Foreign Government from the FDA.

The above steps cover the modification of the devices. However, at the same time, the adaptor must be pursued. Once the design of the protected lead/shroud is identified, an adaptor that is compatible with our modified/protected leads - - and also compatible with the Medtronic interface cable or pulse generator - - would be identified. All customers would need to be notified to purchase this adaptor in order to use the modified Pacing products. The customer would need to purchase the adaptor and determine whether the adaptor would impact use of the pulse generator with other devices; the permanent adaptor might not be compatible with other devices that might be used, thus creating additional issues for the customer.

As demonstrated, the change in leads to meet the requirements is not simply a matter of purchasing the protected lead/shroud and implementing it on the product. In addition, the adaptor has issues associated with its use as well. Thus, Baxter's request for a 180-day variance to allow Baxter to meet the requirements of the performance standard and to allow customers to acquire appropriate adaptors without interrupting availability of the Pacing products is considered to be reasonable.

If you have any questions regarding the information provided in this amendment, please feel free to call me at (949) 250-2418.

Sincerely,



Paula A. Torrianni

Manager, Regulatory Affairs

CardioVascular Group

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